August 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: (1) Section 303 – Docket No. 02N-0275 (Detention)
(2) Section 305 – Docket No. 02N-0276 (Registration)
(3) Section 306 – Docket No. 02N-0277 (Recordkeeping)
(4) Section 307 – Docket No. 02N-0278 (Prior Notice)

Dear Sir/Madam:

The undersigned are a coalition of trade associations (see Attachment A) representing all tiers of the beverage alcohol industry. Members of our associations are involved in the production, importation, distribution/wholesaling, and retailing of beverage alcohol products that are sold throughout the United States.

On behalf of our respective members, we welcome the opportunity to provide initial comments concerning the Food and Drug Administration's (FDA) proactive efforts to liaise with the foods community in implementing the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Act). We fully support this FDA initiative, which is designed to create a focused regulatory scheme that does not unnecessarily duplicate existing statutory and/or regulatory requirements currently in place. To that end, our comments focus upon how the directives of the above-referenced Sections of the Act already are met and satisfied by the existing extensive regulatory scheme governing beverage alcohol.

Since the 1930s, the Bureau of Alcohol, Tobacco and Firearms (BATF) and its predecessor agencies have regulated the beverage alcohol industry in terms of both import and domestic trade.[1] BATF has a comprehensive set of regulations that governs the production, manufacture, importation, and distribution of beverage alcohol products. All persons engaged in the business of producing, importing and distributing beverage alcohol products in the United States must obtain a permit from BATF or be registered with BATF. The beverage alcohol industry also is governed by an extensive regulatory scheme administered by BATF, which, among other things, requires industry members to strictly account for all products. Simply put, the existing regulations enforced by BATF more than satisfy the provisions of this Act.

[1] See generally, Federal Alcohol Administration Act, 27 U.S.C. §§ 121-211, Intemal Revenue Code 26 U.S.C. §§ 5001-5691, and Title 27, Code of Federal Regulations.

In addition, industry members involved in the production, importation and distribution of beverage alcohol products are licensed by each State in which they do business. Each State also has regulations that require recordkeeping and mandate the filing of periodic reports of beverage alcohol products shipped into and/or sold in that State. Although excluded from the scope of the Act, beverage alcohol retailers also are licensed by the States in which they do business.

The U.S. Customs Service further regulates importers of beverage alcohol products. Importers must maintain records to establish upon request that goods imported have been classified correctly, taxes have been paid, and the importer of record has complied with all regulations specifically dealing with beverage alcohol. Further, as discussed more fully below, Customs has several initiatives in place, such as the Container Security Initiative, that requires extensive information about U.S. bound shipments at least 24 hours before the vessel sails to the United States.

We urge FDA to avoid proposing or adopting regulations that would be duplicative of regulations already in place and administered by other federal agencies. In that regard, Sections 302(c) and 314 clearly contemplate and direct the efficient use of government resources to effectuate the goals of this Act and to facilitate its implementation by a clear allocation of federal agency activities. This clear allocation of responsible action among federal agencies, such as BATF and the Customs Service vis-à-vis their respective regulatory schemes governing beverage alcohol, will best utilize the procedures and processes already in place to most efficiently "develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply," the stated purpose of Title III of the Act.

Duplicative regulations and unnecessary regulations are costly and create inefficiencies, as well as spawn potential confusion within the regulated community. Further, such measures impose unnecessary burdens upon regulators and the regulated community and thereby divert valuable time and resources away from government and industry efforts to protect the food supply from bioterrorist threats -- an objective that all of us fully support.

Finally, we urge that the resources and appropriations allocated to implement the Act be available to the federal agencies, such as BATF, that are a critical component in effectuating its provisions. In addition, such agencies also should have available the necessary resources and funds to meet various procedural elements of the Act, such as the electronic filing directive set forth in Section 305(d).

The following are our comments regarding specific Sections of the Act.

Section 303 – Administrative Detention

No person can hold a federal permit to produce, import or distribute beverage alcohol if that person has been convicted of a felony within five years prior to the date of application or within three years of the date of application to have been convicted of a misdemeanor relating to beverage alcohol. Without a permit, importers, distillers, vintners, and distributors cannot

engage in the beverage alcohol business. Permits can be revoked or suspended for reasons specified in federal law. The current permit system for beverage alcohol producers, importers and wholesalers/distributors is far more restrictive and gives the government greater control than anything contemplated in instant Act.

Section 305 – Registration of Food Facilities

Requiring a producer, importer, or distributor of beverage alcohol to register with FDA would be a duplication of existing licensing and/or permit requirements. All importers, domestic producers and wholesalers/distributors of beverage alcohol must obtain a permit from the federal government. While brewers are not required to obtain a permit, they must register with BATF. Any applicant for a permit or registration with BATF must go through extensive background and financial investigations. Foreign producers can only import beverage alcohol through an entity that holds a Federal Basic Importer's Permit.

Section 306 – Maintenance and Inspection of Records for Foods

Under current federal laws and regulations, importers, producers and distributors/ wholesalers of beverage alcohol must maintain "one up and one down" records. During normal business hours, these records must be kept and made available for review by a federal officer. The objectives of Section 306 are met or exceeded by current BATF recordkeeping requirements/regulations. Any additional recordkeeping requirement by FDA would be duplicative and unnecessary.

Section 307 – Prior Notice of Imported Food Shipment

The U.S. Customs Service already receives advance notice of the arrival of a ship and of the ship's manifest well in advance of the ship's arrival. Given the Customs Service's various security initiatives, there is no need for FDA to issue more regulations that would require something already required by the U.S. Customs Service. For example, Customs is in the process of finalizing its new requirements that would require ocean carriers and non-vessel-operating common carriers to present detailed cargo manifests 24 hours before a container is loaded onto a ship. Shippers – food importers – play a crucial role in satisfying these requirements.

The Custom's checklist requires fifteen (15) information elements that are far more detailed than the directives of the Act. These information elements are: (1) foreign port of departure; (2) carrier SCAC code; (3) voyage number; (4) date of scheduled arrival in first U.S. port; (5) numbers and quantities from carrier's master or house bill of lading; (6) first port of loading, or first port of receipt, of the cargo by the inbound carrier; (7) a precise description (or the Harmonized Tariff Schedule numbers if the HTS classification is provided by the shipper) and weight of the cargo, or, if the container is sealed, the shipper's declared description and weight of the cargo (generic descriptions, specifically freight-all-kinds, general cargo, and STC (said to contain) are not acceptable); (8) shipper's name and address, or an identification number, from all bills of lading; (9) consignee's name and address, or the owner's or owners' representative's name and address, or an identification number, from all bills of lading; (10) advise Customs when actual boarded quantities do not equal quantities indicated on the relevant bills of lading (carriers

are not required to verify quantities in sealed containers); (11) vessel name, national flag and vessel number; (12) foreign country of origin where cargo is loaded onto vessel; (13) hazardous-material indicator; (14) container number (for containerized shipments); and (15) seal number affixed to container.

Customs' efforts to improve security impose requirements beyond the dictates set forth in the Act. U.S. companies must educate their suppliers not only about the new manifest rules referenced above, but also about the Customs-Trade Partnership Against Terrorism (C-TPAT) and other security measures. Although technically a voluntary program, C-TPAT is becoming an industry standard.

Conclusion

In summary, we recommend that FDA meet with other agencies that have regulations and jurisdictions to govern the importation, production and distribution of beverage alcohol in order to coordinate responsibilities. Such a liaison will avoid duplication of government resources, government manpower and government regulation. We submit that this suggested course of action will enable the federal government and the food industry to focus their resources more efficiently and effectively upon efforts that will enhance security and will avoid unnecessary and redundant burdens that otherwise could be imposed upon both enforcement and compliance efforts.

Thank you for the opportunity to present our views concerning FDA's actions to implement the Bioterrorism Act. We stand ready to work with you at any time to assist FDA in the development of implementing regulations that will result in the efficient and effective implementation of this Act. If we can be of any further assistance, please do not hesitate to call on us.

Sincerely,

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